510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K073487

FEB 11 2008

1. Submitter name, address, contact	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034	
	U.S. Telephone: U.S. Fax:	469-230-0959 972-317-7861
	Contact Person:	Stephanie G. Donnelly
	Date Prepared:	December 11, 2007
2. Device name	Proprietary Name:	Olympus IgM reagent (OSR6X173)
	Common Name:	IgM reagent
	Classification Name:	IgM (mu chain specific), antigen, antiserum, control.
3. Predicate device	Reagent:	Olympus (OSR6X46) IgM Reagent Submitted K950900
4. Device description	In this Olympus procedure: • When a sample is mixed with R1 buffer and R2 antiserum solution, human IgM reacts specifically with anti-human IgM antibodies to yield insoluble aggregates. • Immune complexes formed in solution scatter light in proportion to their size, shape and concentration. • Turbidimeters measure the reduction of incidence light due to reflection, absorption or scatter. • In the Olympus procedure, the decrease in intensity of light transmitted (increase in absorbance) through particles suspended in solution is as a result of complexes formed during the antigen-antibody reaction.	
5. Intended use	System reagent for the quantitative determination of IgM immunoglobulins in human serum and plasma on OLYMPUS analyzers. For *in vitro* diagnostic use.	

6. The following Tables compare the new Olympus IgM (OSR6X173) reagent with the predicate device outlined in point 3 above.

Similarities		
Item	Olympus IgM (OSR6X173) reagent	Predicate System
Intended Use	System reagent for the quantitative determination of IgM immunoglobulins in human serum and plasma on OLYMPUS analyzers.	System reagent for the quantitative determination of IgM immunoglobulins in human serum on OLYMPUS analyzers.
Instrument	Olympus AU400/400^{e}, 600/640/640^{e} and 2700/5400	Same
Measurement	Quantitative	Same
Reagent handling	Ready for use	Same
Assay Methodology/Operating Principle	Immunoturbidimetric	Same
Antibody	Goat anti-IgM antiserum	Same
Reagent storage form	Liquid On–board storage	Same
On-Board Stability	90 days	Same
Calibrator	Olympus Serum Protein Mulit-Calibrator (ODR3021)	Same
Calibrator Traceability	This method is traceable to the International Reference Preparation CRM470 (US designation RPPHS lot 91/0619)	Same
Calibration Frequency	90 days	Same
Expected Values	45-281 mg/dL	Same

Differences		
Item	Olympus IgM (OSR6X173) reagent	Predicate System
Specimen Type	Serum and plasma: Li -heparin and EDTA plasma	Serum

Performance Characteristics		
Item	Olympus IgM (OSR6X173) reagent	Predicate System
Precision	AU400/400^{e} Sample Total CV% 1 4.03 2 2.95 3 2.60 AU600/640/640^{e} Sample Total CV% 1 3.44 2 3.29 3 4.08	AU400/400^{e} Sample Total CV% 1 1.74 2 1.18 3 1.49 AU600 Sample Total CV% 1 2.16 2 1.48 3 1.35 AU640/640^{e} Sample Total CV% 1 1.5 2 1.3

	AU2700/5400 Sample Total CV% 1 3.79 2 3.31 3 3.52	AU2700/5400 Sample Total CV% 1 2.49 2 2.57 3 3.07
Assay Range	20-500 mg/dL	Same
Prozone	Hook effect may occur with highly elevated IgM samples > 10, 000 mg/dL polyclonal	Hook effect may occur with highly elevated IgM samples > 3, 500 mg/dL polyclonal
Method Comparison (Linear Regression)	Slope 1.006 Intercept 2.8 R^2 1.000 N 107 Range 22-468 mg/dL	Slope 0.968 Intercept 0.6 R^2 0.998 N 96 Range 24-497 mg/dL
Interfering Substances	AU400/400[e] Bilirubin: Interference less than 4% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 4% up to 500 mg/dL Hemolysate Lipemia: Interference less than 10% up to 300 mg/dL Intralipid Not Tested AU600/640/640[e] Bilirubin: Interference less than 3% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 3% up to 500 mg/dL Hemolysate Lipemia: Interference less than 10% up to 300 mg/dL Intralipid Not Tested AU2700/5400 Bilirubin: Interference less than 8% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 3% up to 500 mg/dL Hemolysate Lipemia: Interference less than 10% up to 200 mg/dL Intralipid Not Tested	AU400/400[e] Bilirubin: Interference less than 2% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 2% up to 500 mg/dL Hemolysate Lipemia: Interference less than 10% up to 300 mg/dL Intralipid Ascorbic Acid: Interference less than 2% up to 20 mg/dL Ascorbate AU600/640/640[e] Bilirubin: Interference less than 5% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 10% up to 500 mg/dL Hemolysate Lipemia: Interference less than 10% up to 400 mg/dL Intralipid Ascorbic Acid: Interference less than 1% up to 20 mg/dL Ascorbate AU2700/5400 Bilirubin: Interference less than 10% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 5% up to 500 mg/dL Hemolysate Lipemia: Interference less than 10% up to 400 mg/dL Intralipid Ascorbic Acid: Interference less than 3% up to 20 mg/dL Ascorbate
Function Sensitivity	< 20 mg/dL on AU400/400[e], AU600/640/640[e] & AU2700/5400	Not Specified

****

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 11 2008

Olympus America, Inc.
c/o Ms. Stephanie Donnelly
Regulatory Affairs/Quality Assurance Manager
Olympus Life Science Research Europa GmbH
Lismeehan, O, Callaghan's Mills
Co. Claire, Ireland.

Re: k073487
Trade/Device Name: Olympus IgM reagent
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, E immunological test systems
Regulatory Class: Class II
Product Code: CFN
Dated: December 11, 2007
Received: December 12, 2007

Dear Ms. Donnelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K073487

Device Name: Olympus IgM reagent (OSR6X173)

Indication For Use: System reagent for the quantitative determination of IgM immunoglobulins in human serum and plasma on OLYMPUS analyzers.

The spectrum of abnormalities in serum immunoglobulin concentrations is broad. Abnormal concentrations range from a virtual absence of one or more of the three major classes of immunoglobulin (IgA, IgG, and IgM) to polyclonal increases in one or more immunoglobulins. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

For *in vitro* diagnostic use.

Prescription Use __✓___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073487